Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT W
WX0000003826 F 12/05/1988 34 Y

Referral Testing

Collected: 07/19/2023 11:22 Received: 07/19/2023 11:22

Test Name	Result	Flag	Ref-Ranges	Units	Site

ADMARK (R) Phospho-Tau/Total-Tau/A Beta42 CSF

Interpretation — See Note — QCRL

This test detected borderline levels of A-beta 42, T-tau and/or P-tau proteins in the cerebrospinal fluid (CSF).

Technical Results — See Note — QCRL

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Interpretive Result Table
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INTERPRETATION: Borderline
TEST: A-beta 42
TECHNICAL RESULT: 508.9 pg/mL
REFERENCE RANGE: Not consistent with AD: P-Tau <54 pg/mL and ATI >1.2,
Borderline: P-Tau 54-68 pg/mL and/or ATI 0.8-1.2, AD: P-Tau >68 pg/mL
and ATI <0.8
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INTERPRETATION:
TEST: T-Tau
TECHNICAL RESULT: 268 pg/mL
REFERENCE RANGE:
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INTERPRETATION:
TEST: P-Tau
TECHNICAL RESULT: 65.65 pg/mL
REFERENCE RANGE:
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INTERPRETATION:
TEST: ATI
TECHNICAL RESULT: 0.91
REFERENCE RANGE:
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Comments — See Note — QCRL

Comments: This analysis detected borderline levels of CSF A-beta 42 peptide (A-beta 42), total tau (T-tau) and/or phospho-tau (P-tau) protein as indicated in the technical results table. The clinical significance of these results is unknown. Please carefully reconcile these results with the patient's clinical symptoms and medical history.

Recommendations: Health care providers, please contact the Athena

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Diagnostics Client Services Department at 1-800-394-4493 if you wish to speak with a clinical consultant regarding this test result.

Background information: Alzheimers disease (AD) is the most common form of dementia, accounting for 60-70% of cases (1). AD manifests initially with subtle progressive memory loss that eventually becomes severe and incapacitating. Behavioral deficits, including social withdrawal, aggression, depression and hallucinations, are also present (3). Pathologically, AD is characterized by the formation of beta-amyloid plaques and neurofibrillary tangles within the brain, and cerebral cortical atrophy (4). The CSF based biomarkers A-beta 42 peptide (A-beta 42), phospho-tau (P-tau) and total tau (T-tau) can aid in the diagnosis of AD. The combination of A-beta 42 and T-tau results are express as the A-beta 42 to T-tau Index (ATI). ATI is calculated as A-beta 42/(240 + 1.18 x T- tau) and represents a ratio normalized by the discrimination line A-beta 42 = 240 + 1.18 x T-tau (4, 5). Studies performed with over 70 participants, showed that the cutoff value of ATI = 1, yields a sensitivity of 85-94% and specificity of 54-95% in distinguishing AD from non-AD populations (4, 5). An ATI of <1.0 is typical of AD, while a value >1.0 is typical of control populations. Additionally, the CSF levels of P-tau have been found to discriminate AD from other dementias with sensitivities of 72-88% and specificities of 78-83% (1). Athena considers ATI values of 0.8 to 1.2 and P-tau levels of 54-68 pg/ml as borderline results. The combination of all three biomarkers has been reported to have an average sensitivity and specificity of 85% and 90%, respectively (6).

Methods	See Note				QCRL

Detection of proteins was performed by Enzyme Linked Immunosorbent Assay (ELISA) methodology.

Limitations of analysis: Although rare, false positive or false negative results may occur. All results should be interpreted in the context of clinical findings, relevant history, and other laboratory data.

References	See Note				QCRL

1. Ferreira, D, et al. (2014) Front Aging Neurosci 6: 47. (PMID: 24715863)
2. Bird, T. (2008) Genet Med 10:231-9 (PMID:18414205)
3. Braak, H, et al. (1991) Acta Neuropathol 82: 239-59. (PMID: 1759558) 4. Hulstaert, F, et al. (1999) Neurology 52: 1555-62. (PMID: 10331678) 5. Blennow, K. (2004) NeuroRx 1: 213-25. (PMID: 15717022) 6. Blennow, K, et al. (2015) Alzheimers Dement 11: 58-69. (PMID: 24795085)

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This test was developed and its analytical performance characteristics have been determined by Athena Diagnostics. It has not been cleared or approved by the U.S. Food and Drug Administration. This assay has been validated pursuant to the CLIA regulations and is used for clinical purposes.

Laboratory oversight provided by Vivekananda Datta, M.D., Ph.D., CLIA license holder, Athena Diagnostics (CLIA# 22D0069726)

Testing performed at:
Athena Diagnostics 200 Forest Street Marlborough, MA 01752
Test Performed at:
Athena Diagnostics, Inc.
200 Forest Street, 2nd Floor
Marlborough, MA 01752 V Datta MD, PhD

Performing Site:
QCRL: QUEST DIAGNOSTICS REFERENCE LAB CAPISTRANO 33608 Ortega Highway San Juan Capistrano CA 92675

Reported Date: 2023.07.19 11:24 ALZE

LAB: L - LOW, H - HIGH, AB - ABNORMAL, C - CRITICAL, . - NOT TESTED